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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,656	01/14/2004	Robert A. Ashley	512-53 DIV	3939

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HOFFMANN & BARON, LLP
6900 JERICHO TURNPIKE
SYOSSET, NY 11791

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,656	ASHLEY, ROBERT A.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,23-29,32,34,36,38 and 46-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,23-29,32,34,36,38 and 46-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *all*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 23-29, 32, 34, 36, 38 and 46-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-34, 46 and 47 of copending Application No. 10/117,709 ('709). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '709 application claims a method of treating acne in a human in need thereof comprising administering orally or intravenously to said human a tetracycline compound in a sub-antibacterial amount that reduces lesion count, said amount being 10-80% of the antibacterial effective amount without administering a bisphosphonate compound (claims 1 and 2). Tetracycline compounds are found in claims 4-22. Non-

antibiotic tetracycline compounds are found in claims 23-34. Thus, the present claims anticipate the claims of the '709 application, because the copending application claims the same method using the same tetracycline compounds, and in the same sub-antibacterial amount.

Claims 1, 2, 23-29, 32, 34, 36, 38 and 46-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 86, 87 and 91-107of copending Application No. 11/061,866 ('866). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '866 application claims a method of treating rosacea in a human in need thereof comprising administering orally to said human a tetracycline compound in an amount that is effective to treat rosacea but has substantially no anti-biotic activity without administering a bisphosphonate compound. The effective amount of tetracycline is found in claims 91 and 92. Tetracycline compounds are found in claims 93-101. Non-antibiotic tetracycline compounds are found in claims 102-106. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of treating rosacea to obtain the claimed method given the claims of the '866 application. There are no unusual and/or unexpected results, which would rebut prima facie obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 23-29, 32, 34, 36, 38 and 46-64 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 7,014,858 ('858). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '858 patent claimed a method for treating telangiectasia associate with acne rosacea in a human in need thereof comprising administering orally or intravenously to said human a tetracycline compound in a sub-antibacterial amount that reduces telangiectasia, said amount being 10-80% of the antibacterial effective amount, and the tetracycline compound is administered long term without a bisphosphonate compound (claims 1 and 2). Tetracycline compounds are found in claims 3-20. Non-antibiotic tetracycline compounds are found in claims 21-30. Thus, the present claims anticipate the claims of the '858, patent because the patent claims the method using the same tetracycline compounds in the same amount for the treatment of acne, namely acne rosacea.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 38 and 46-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arbiser US 6,673,843, in view of Webster et al. (Antimicrobial agents and Chemotherapy) or Plewig et al. (Acne).

Arbiser teaches a method for treating diseases or disorders of the skin such as verruca vulgaris, acne, and rosacea (abstract; and column 2, lines 66 through column 3, lines 1-10). The method comprising administering orally or parenterally a composition comprising an angiogenesis inhibitor agents, preservative, antioxidants, antibiotics, and other biologically or pharmaceutically effective agents (column 6, lines 66 through column 7, lines 1-45). Angiogenesis inhibitor agents include tetracycline such as minocycline, doxycycline, and chemically modified tetracycline compounds (CMT, non-antibiotic compounds) (column 4, lines 1-51).

Arbiser does not explicitly teach the claimed sub-antibiotic amount. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the present case, Arbiser teaches the use of tetracycline compounds having collagenase inhibitory activity (substantially no antibiotic activity) for the same treatment, namely acne rosacea. To be more specific, Webster teaches that a subminimal inhibitory concentration of antibiotics such as tetracycline, ampicillin, minocycline, and erythromycin, is capable of reducing the inflammatory capacity of *P. acnes* (abstract in page 770). Plewig teaches a method for the treatment of acne using tetracycline compounds in a non-bacteriostatic concentration (page 300). Thus, it would have been obvious to one of ordinary skill at the time the claimed invention was made to, by routine experimentation determine a

suitable sub-antibiotic amount of tetracycline compounds in view of the teaching of Webster, because Webster teaches the use of tetracycline compounds in a *sub-minimal amount*, because Webster teaches the use of tetracycline in an amount that can inhibit the production of neutrophil chemotactic factors in susceptible strains of P. acnes (page 772), and because Plewig teaches low dose of tetracycline compounds with blood levels appreciably less than required is safe for long term treatment of acne.

Claims 1, 2, 23-29, 32, 34 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arbiser US 6,673,843, in view of Webster et al. (Antimicrobial agents and Chemotherapy) or Plewig et al. (Acne), and McNamara et al. US 4,704,383.

Arbiser is relied upon for the reason stated above. Arbiser does not expressly teach the claimed sub-antibacterial amount of tetracycline compounds. Arbiser further does not teach the claimed non-antibiotic tetracycline compounds.

McNamara teaches a composition comprising tetracycline having substantially no effective antibiotic or antibacterial activity for oral administration (abstract; and column 10, lines 16-34). Tetracycline includes CMT compounds (columns 9-10). Thus, it would have been obvious to one of ordinary skill at the time the claimed invention was made to modify the composition of Arbiser using the non-antibiotic tetracycline compounds of McNamara in a sub-antibacterial amount, because McNamara teaches using non-antibiotic tetracycline compounds in a minimum inhibitory concentration to obtain a composition useful for long term treatment without any usual complications (column 1, lines 58-64; and column 4, lines 53-57), because McNamara teaches the use of non-

antibiotic compounds that possess anti-collagenase activity , and because Arbiser teaches antibiotics having collagenase inhibitory activity.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arbiser US 6,673,843, in view of Ramamurthy et al. US 5,998,390.

Arbiser is relied upon for the reason stated above. Arbiser does not expressly teach the claimed non-antibiotic tetracycline compound.

Ramamurthy teaches a composition useful for the treatment of MMP-dependent conditions comprising CMT compound includes 6-demethyl-6-deoxy-4-de(dimethylamino)tetracycline compound (column 7, lines 46-67). Thus, it would have been obvious to one of ordinary skill in the art to use the CMT compound in view of the teaching of Ramamurthy as an angiogenesis inhibitor agent, because Ramamurthy teaches the use of pharmaceutically known tetracycline compounds such as 6-demethyl-6-deoxy-4-de(dimethylamino)tetracycline, doxycycline, and minocycline, and because Arbiser teaches the use of commercially available tetracycline compounds including CMT, doxycycline, and minocycline.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Amin et al., and McNicol et al. are cited as of interest for the teachings of composition using non-antibiotic compounds for the treatment of acne.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R 6:00 am to 4:30 pm; Tues. (telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Patent Examiner
Art Unit 1615